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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,089	10/14/2004	Masamichi Yuda	Q84158	7188

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	PAPER NUMBER
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,089	YUDA ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 14Oct04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

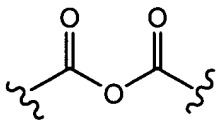
Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

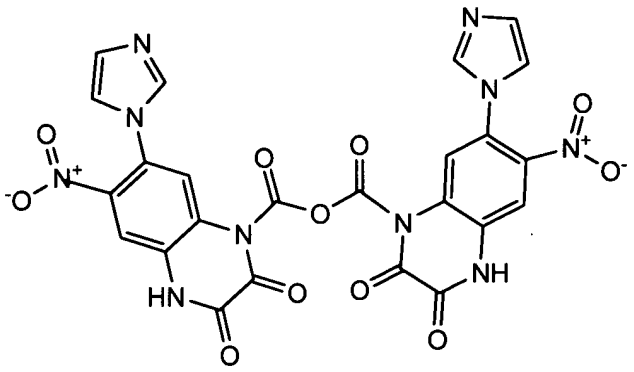
The following is a quotation of the first and second paragraphs of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the claims recite an *anhydride* of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid. As understood by the chemist of ordinary skill, an *anhydride* of a carboxylic acid includes a structural moiety represented by the diagram following:



Therefore, the *anhydride* of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid would have the structure represented by the diagram below:



No teaching as to how this anhydride compound is prepared is provided in the disclosure. In other words, the claimed anhydride of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid is not enabled. Because synthesis of the claimed anhydride compound is nowhere taught in the instant specification, the factors from the decision rendered *In re* Wands*, the so-called "Wands factors," which are customarily relied upon in a finding of non-enablement have *not* been reviewed here. It is self-evident that the claimed subject matter is not enabled. Should this rejection be of further issue, the Wands factors will be reviewed in a subsequent Office action.

For the purposes of this Office action, claim 1 has been examined on the merits as though it specified an *anhydrous* form of the compound named therein, instead of an "anhydride" form of the compound.

**In re Wands*, 858 F.2d 731,737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 specifies an "α crystal of free form anhydride" of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid. The term "α crystal" is not defined in the instant specification such that its meaning within the context of the instant claims is clear and well-defined. In the instant specification, it is established that there are two crystalline forms of the compound, an α form and a β form, but in the absence of accompanying powder X-ray diffraction (PXRD) data for each respective form, these designations do not serve to describe any special physical characteristics of those compound's crystalline forms (the broadest claim, claim1, does not include any PXRD data). In other words, the "α" and "β" designations are arbitrary and specific to the compound thus designated; they do not carry any significance generally, which would be applicable to all compounds.

Also in claim 1, the compound is characterized as the "free form" compound. This is not defined in the specification such that its significance is clear and well-defined either. Absent some definition of the term in the disclosure, the term "free form" in the claims might be interpreted by the skilled chemist as referring to some *non*-crystalline form, in other words, an amorphous form of the compound. If so, then, the claims are self-contradictory – specifying both the "free form" and the crystalline form of the compound. Applicants should delete "free form" from the claims, as its recitation is not necessary to define the invention, if the invention is indeed a crystalline form of the named compound, wherein that crystalline form has certain PXRD characteristics.

Claim 1 (and any claim depending from that claim) has been examined on the merits as though it did not specify "α crystal," "free form" or "anhydride." Claim 1 has been examined on the merits as though it read as follows:

> 1. An anhydrous crystal form of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid.

In addition to being rejected under 35 U.S.C. 112, second paragraph, because is depends from indefinite base claims, claim 7 provides for the use of the α crystal according to any one of claims 1 to 3 for manufacturing a pharmaceutical, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,096,743 (Shishikura et al) or EP 0 784 054 (Shishikura et al).

US 6,096,743 and EP 0 784 054 are equivalents. The U.S. patent was published 1 August 2000; the EP document was published 16 July 1997.

Example 1 in both the U.S. patent (col. 14, at lines 46-55) and the EP document (page 12, at lines 48-50) describes synthesis of [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid – named "2-[2,3-dioxo-7-(1H-imidazol-yl)-6-nitro-1,2,3,4-tetrahydroquinoxalin-1-yl] acetic acid" in the references. The substance, according

to the cited references, is isolated as crystals from an acidic aqueous solution, as the hydrochloride salt hydrate.

The compound according to Example 1 in the references is taught to have utility as an AMPA receptor antagonist and for treating cerebral infarction. These teachings necessarily contemplate preparation of the compound as a pharmaceutical composition, in particular a pharmaceutical composition as an injectable aqueous solution. When the compound according to Example 1 of the references is prepared thusly, it is embraced by instant claims 5, 6 and 8, wherein the subject matter of instant claims 5, 6 and 8 is in the form of an injectable aqueous solution. According to the instant specification, the AMPA antagonist (according to claim 5) and pharmaceutical composition (according to claim 6) comprising the crystalline form according to instant claim 1 are preferably presented as an injectable aqueous solution (pages 9 and 10). When prepared as an aqueous solution, the crystal dissolves and becomes associated with water molecules in solution, thus the substance described in Example 1 of either reference, when dissolved in aqueous solution as an injectable pharmaceutical composition, is embraced by instant claims 5 and 6, and therefore is within the scope of instant claim 8, insofar as its taught utility is concerned, when administered as said injectable solution.

Allowable Subject Matter
~and~
Close Prior Art

Claims 2-4 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

It is recommended that applicants rewrite instant claim 2 as follows, and cancel instant claim 1, in order to place claims 2-4 in condition for allowance. Claim 5 should be

cancelled as well, because it is redundant (duplicates subject matter of both the base claim and the pharmaceutical-comprising-claim). Claim 8 should be amended so that it depends from claims 2 to 4 in the alternative.

2. ~~The~~ An α crystal ~~according to claim 1,~~ of anhydrous [7-(1*H*)-imidazol-1-yl)-6-nitro-2,3-dioxo-3,4-dihydroquinoxalin-1(2*H*)-yl] acetic acid wherein the α crystal exhibits peaks at diffraction angles of 9.1°, 19.4°, 22.5°, 23.3°, 23.9°, 25,7° and 26.2° in X-ray powder diffraction patterns.

The closest prior art with respect to the subject matter indicated as being allowable herein is the two references cited in the rejection under 35 U.S.C. 102, in this Office action. Also of interest, but not relied upon in any claim rejection, is US 6,288,065 (Huth et al), which teaches quinoxaline-carboxylic acid derivatives which have utility as centrally active AMPA antagonists, for treatment of Parkinson's disease.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

ZACHARY C. TUCKER
PRIMARY EXAMINER